

REMARKS

Claims 96-143 are pending in the present application. Claims 97-110 and 116-143 have been withdrawn from consideration. By the present Amendment, claims 111 and 113 have been amended. This application continues to include claims 96-143.

The Examiner “notes that the kind code, issue date, and Name of Patentee or Applicant do not match the Patent Number for Cite No 1 of Applicant’s 16 July 2010 IDS.” The Examiner then changed citation number 1 to a reference that discloses a gas burner. The Examiner’s assessment and change do not correspond to Applicants’ intent. The IDS Form SB08a of July 16, 2010, properly identified the kind code as “E”, which is the correct kind code for a reissue patent, as shown in the excerpt from the face page of the reissue patent below.

<b>United States Patent</b> [19]	[11] E	<b>Patent Number:</b>	<b>Re. 33,258</b>
<b>Onik et al.</b>	[45] Reissued	<b>Date of Patent:</b>	<b>Jul. 10, 1990</b>

[54] <b>IRRIGATING, CUTTING AND ASPIRATING SYSTEM FOR PERCUTANEOUS SURGERY</b>	4,210,146 7/1980 Banko ..... 128/305 4,493,694 1/1985 Wuchinich ..... 604/22 4,513,745 4/1985 Amols ..... 128/305 4,517,977 5/1985 Frost ..... 128/305
[75] <b>Inventors:</b> Gary Onik, San Francisco; Leonard Ginsburg, Oakland, both of Calif.	

[73] **Assignee:** Surgical Dynamics Inc., San  
Leandro, Calif.

[21] **Appl. No.:** 126,905

[22] **Filed:** Nov. 30, 1987

**FOREIGN PATENT DOCUMENTS**

1235321	6/1971	United Kingdom	128/305.1
2018601	10/1979	United Kingdom	128/305

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**Related U.S. Patent Documents**

Reissue of:

[64]	Patent No.:	4,678,459	
	Issued:	Jul. 7, 1987	
	Appl. No.:	633,514	
	Filed:	Jul. 23, 1984	

[51]	Int. Cl. <sup>3</sup> .....	A61B 17/32
[52]	U.S. Cl. ....	604/22; 606/171
[58]	Field of Search .....	128/305, 305.1, 751, 128/752, 755; 604/22

[56] **References Cited**

**U.S. PATENT DOCUMENTS**

3,732,858	5/1973	Banko .....	128/2 B
3,815,604	6/1974	O'Malley et al. ....	128/305
3,844,272	10/1974	Banko .....	128/2 B
3,884,238	5/1975	O'Malley et al. ....	128/305

[57] **ABSTRACT**

A percutaneous discectomy system 10 includes a discectomy device 12 having a needle 16 with a port 48 and a flared cutting edge 44 which is actuated past the port 48 to sever tissue provided adjacent thereto. An irrigation device is 18 are provided for irrigating the area adjacent the tip 46 of the needle 16 to assist a vacuum device 22 in aspirating the severed tissue away from the disc. The discectomy system 10 assists in the removal of herniated disc tissue in order to relieve pressure on the nerves located adjacent thereto. In addition, the needle 16 is flexible so that it can be temporarily or permanently bent around other body tissues such as the pelvis in order to access discs which are surgically hard to reach otherwise.

**13 Claims, 3 Drawing Sheets**

In this case, the patent number is Re. 33,258, and the number was entered in the form as 0033258. Re. 33,258 is a reissue of US 4,678,459. It is respectfully requested that the Examiner either change the Form SB08a of July 16, 2010, to designate Re. 33,258, or change the Patent Number field to the pre-reissue patent number of 4,678,459. Also, in either case, consideration of Re. 33,258/ US 4,678,459 is respectfully requested.

The Examiner objects to Amendment of May 9, 2008, and asserts that the Amendment introduces new matter into the disclosure by incorporating by reference material that was not previously incorporated by reference in paragraph 0001, which makes reference to the foreign priority documents. To address the Examiner's concerns, previously amended paragraph 0001 has been amended by the present Amendment to remove the language, “, the entireties of which are hereby incorporated by reference”.

Accordingly, it is respectfully requested that the objections to the specification be withdrawn.

Claims 111-115 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The Examiner asserts that in claim 111, the reference to “secondary transmission” is unclear. Claim 111, in its prior form recites, “The biopsy device according to claim 96, wherein the tension slide is displaced to the cocked position by rotation of a spindle actuator, the spindle actuator being driven by a DC gear motor with a secondary transmission drivably coupled to the spindle actuator.” Applicants respectfully submit that claim 111 is clear in context, as the spindle actuator is driven by a DC gear motor with a secondary transmission drivably coupled to the spindle actuator. It is presumed that the Examiner is not taking issue

with the term “transmission” but rather to the label “secondary”. In an attempt to address the Examiner’s concerns while avoiding confusion with the “planetary transmission” recited in claim 114, claim 112 has been amended to change the term “secondary transmission” to “transmission mechanism”.

Further, it is respectfully submitted that the change of terminology from “secondary transmission” to “transmission mechanism” does not raise new issues, and should be entered. Notwithstanding the Examiner’s objection to the term “secondary transmission”, there would have been nothing in the term “secondary transmission” to make claim 111 so unclear as to prevent the Examiner from giving the term its broadest reasonable interpretation for purposes of substantive examination, i.e., the spindle actuator being driven by a DC gear motor with a transmission drivably coupled to the spindle actuator. Accordingly, with the change of terminology from “secondary transmission” to “transmission mechanism”, and with no substantive grounds for rejection of claim 111 being provided, it is respectfully submitted that the subject matter of claim 111 is in condition for allowance in its own right.

With respect to claim 112, the Examiner states that it is unclear what limitation(s) claim 112 adds to claim 111, as the limitation appears to already be in claim 96. Claim 96 recites in part, “the tension slide being locked in the cocked position by a releasable locking mechanism....” Claim 111 which depends from claim 96 recites, “tension slide is displaced to the cocked position by rotation of a spindle actuator”, and does not address locking of the tension slide. Claim 112 which depends from claim 111 recites in part, “wherein the tension slide is configured to be mechanically locked in the cocked position. Thus, claim 112

specifies that the tension slide contributes to the locking by its configuration. Accordingly, it is respectfully submitted that claim 112 is clear in its present form.

Claim 113 was considered as unclear as to whether the double-arm lever was considered to be the same structure or different structure from the releasable locking mechanism of claim 96. Claim 113 has been amended to depend directly from claim 96 and to clarify that the “releasable locking mechanism comprises a double-arm lever configured to mechanically lock the tension slide in the cocked position, the double-arm lever being adjusted about an axis under spring pressure, wherein a first arm is acted upon by a pressure spring, and a second arm engages with a recess of the tension slide.” (Emphasis added).

Further, it is respectfully submitted that the amendment to claim 113 does not raise new issues, and should be entered. Accordingly, with clarifying that the releasable locking mechanism comprises a double-arm lever, and with no substantive grounds for rejection of claim 113 being provided, it is respectfully submitted that the subject matter of claim 113 is in condition for allowance in its own right.

Claims 114 and 115 were rejected as ultimately depending from claim 112, and thus are clear for reasons set forth above with respect to claim 112.

Accordingly, it is respectfully requested that the rejection of claims 111-115 under 35 U.S.C. §112, first paragraph, be withdrawn.

Claim 96 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,989,614 (Dejter, Jr. et al.; hereinafter Dejter).

Claim 96 recites:

A biopsy device for taking tissue samples, comprising: a housing containing an electric power source and a tension slide connected to the

power source, wherein the tension slide is brought into a cocked position against the action of a first spring by the power source, the tension slide being locked in the cocked position by a releasable locking mechanism; a removable element configured for insertion into the housing, comprising: **a biopsy needle unit, comprising a hollow biopsy needle, having a sample removal chamber, and a cutting sheath**, wherein the biopsy needle unit is arranged on the tension slide; a vacuum pressure-generating device; and a connection element connecting the biopsy needle unit and the vacuum pressure-generating device; and a control panel attached to the housing. (Emphasis added).

The Examiner asserts in response to Applicants' prior arguments in support of patentability that "it is noted that the features upon which applicant relies (i.e., "a sheath that cuts" (or a sheath configured to cut tissue)) are not recited in the rejected claim(s). Applicants respectfully disagree, in that the term "cutting sheath" recited in claim 96 is clearly recited as a part of the "biopsy needle unit". Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms. See *Vitronics*, 90 F.3d at 1582; see also *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 [68 USPQ2d 1516] (Fed. Cir. 2003) ("the context of the surrounding words of the claim also must be considered in determining the ordinary and customary meaning of those terms"). *Phillips v. AWH Corp.*, 75 USPQ2d 1321, 1327 (Fed. Cir. 2005). In claim 96, it is recited a **"biopsy needle unit, comprising a hollow biopsy needle, having a sample removal chamber, and a cutting sheath"**, and thus claim 96 leaves no doubt that the cutting sheath is a sheath that cuts, i.e., is a sheath configured to cut tissue.

In rejecting claim 96, the Examiner takes the position that sheath 6 of Dejter corresponds to the recited cutting sheath. Such a position simply is not supported by Dejter. The sheath 6 of Dejter is a support for needle 2 and stylet 3, and is not a cutting sheath, i.e., a sheath that cuts, nor is Dejter sheath 6 used in any manner to sever tissue. In rejecting claim 96, the Examiner appears to discount limitations of the claim in order to support the rejection, which is improper. The Federal Circuit has held in *In re Suitco Surface* that the Board of Patent Appeals and Interferences unreasonably construed a claim regarding a plastic floor covering by disregarding the limitation that the patented covering was indented to be the final finishing surface for the floor, the U.S. Court of Appeals for the Federal Circuit ruled April 14 (*In re Suitco Surface Inc.*, Fed. Cir., No. 2009-1418, 4/14/10). Similarly, the claim limitation of a “cutting sheath” cannot be disregarded when applying Dejter to claim 96.

In Dejter sheath 6 includes a finger guard 13, or a sheath handle 14, to assist the operator in manipulating the tip of the sheath. (Dejter column 8, lines 56-66). In addition, the cutting/collection of cells occurs by the reciprocation of the needle 2 within a target area, with the aid of vacuum (see, e.g., Dejter column 7, lines 26-46). Thus, Dejter does not disclose, teach or suggest that sheath 6 is a cutting sheath, as recited in claim 96, nor does Dejter disclose, teach or suggest a cutting sheath in any fashion.

Further, while Dejter discloses a mechanism by which the needle is reciprocated, it is respectfully submitted that such does not constitute “a tension slide connected to the power source, wherein the tension slide is brought into a cocked position against the action of a first spring by the power source, the tension slide being **locked** in the **cocked position** by a releasable locking mechanism”, as recited in claim 96. The term “cocked” in the present

specification refers to a locking of the tension slide. (See Applicants' specification at paragraph [0072]). In contrast, assuming arguendo that Dejter discloses a tension slide, there is no locking/cocking of the slide against the action of a spring. Rather, Dejter discloses that a forward thrust of the needle to take a tissue sample is performed by actuation of the solenoid 70 against return springs 61 (i.e., the needle is extended to position "B" into the tissue to take the tissue sample), and a return reciprocation to the home position is performed under the bias of return springs 61 when the solenoid 70 is deactivated. (See, e.g., Dejter column 14, lines 33-38). Thus, to the extent that Dejter discloses a tension slide, the operation of the tension slide is opposite to that recited in claim 96, and more particularly, Dejter does not bring the tension slide into a "cocked position" against the action of a spring by the power source.

The Examiner further asserts, however, that Applicants' arguments would not apply if the forward extent position B achieved in Dejter (see Dejter Figs. 1b and 1e) was considered to be the "cocked position". The Examiner has not explained, however, why one of ordinary skill in the art would reasonably consider the forward extent position B wherein the needle tip penetrates the tissue (Dejter column 13, line 58-column 14, line 4) to be a "cocked" position. Such a scenario would equate the position achieved after the work has been achieved, i.e., after the forward thrust position where a tissue sample is acquired, to be the cocked position. By analogy, such would be the like saying that a baseball pitcher has not cocked his/her arm until after achieving the forward extent of the throw, when clearly the opposite is the case.

Moreover, Dejter never discloses achieving a locked/cocked position, nor does Dejter disclose a tension slide being locked in the cocked position by a releasable locking mechanism. Rather Dejter discloses repetitive reciprocation (Dejter column 14, lines 33-38),

similar in motion to that of a needle of a sewing machine, between the rearward position C and the forward position B to acquire a biopsy sample.

Thus, it is respectfully submitted that claim 96 is not anticipated or rendered obvious by Dejter.

Accordingly, it is respectfully requested that the rejection of claim 96 under 35 U.S.C. §102(b) as being anticipated by Dejter, be withdrawn.

For at least the reasons set forth above, the present application is believed to be in condition for allowance in its present form, and it is respectfully requested that the Examiner so find, rejoin the withdrawn claims, and issue a Notice of Allowance in due course.

In the event Applicants have overlooked the need for an extension of time, an additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No. 50-5242, RONALD K. AUST, P.C.

Should any questions concerning the foregoing arise, the Examiner is invited to contact the undersigned at (317) 894-0801.

Respectfully submitted,  
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